REMARKS

I. Restriction Requirement

In the above referenced Office Action, the Examiner divided the claims into the following groups:

Group I (Claims 1-14 and 30-34) is drawn to an antibacterial compound consisting of a substantially uncharged antisense oligomer and compositions (livestock and poultry food) comprising the antibacterial compound, classified in class 536, subclass 24.5.

Group II (Claims 15-29) is drawn to a method of treating a bacterial infection in a human using a substantially uncharged antisense oligomer, classified in class 514, subclass 44.

Applicants hereby elect Group II, which includes and is drawn to claims 15-29, for examination in the present application. In accord with 37 C.F.R. § 1.143, the claims to non-elected subject matter are cancelled consistent with this election. Applicants reserve the right to prosecute the subject matter of non-elected claims in subsequent divisional applications.

II. Further Restriction Requirement

The Examiner has imposed a further restriction on Groups I and II. Specifically, the Examiner has stated that pursuant to 35 U.S.C. § 121 and 37 C.F.R. § 1.141, the antisense sequences listed in claims 11, 13, 14, 23, 25, 26 and 34 are subject to restriction. Applicants respectfully traverse this further restriction for at least the reasons set forth below.

A. A search of ten sequences is considered a reasonable number for examination purposes

As noted by the Examiner, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996). M.P.E.P. § 803.04 and § 2434.

M.P.E.P. § 803.04 states the following:

> "It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined."

The following example claim is set forth in M.P.E.P. § 803.04: "A combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000." In this example, the Office requires Applicants to select one combination for examination. If the selected combination contains ten or fewer sequences, all of the sequences of the combination will be searched.

In the present case, with respect to the claims in elected Group II, Applicants have amendmed claim 15 to require that the targeting sequence be selected from the group consisting of SEQ ID NOs: 15, 16, 21-25, and 28-30. As such, the sequences presently claimed now total ten (SEQ ID NOs: 15, 16, 21-25 and 28-30). Because the selected combination contains ten or fewer sequences, based on the guidelines set forth in M.P.E.P. § 803.04, all of the sequences of the combination should be searched.

B. Practice regarding Markush-type claims

Further, Applicants object to the Examiner dividing the subject matter of Applicants' claimed invention, as claimed in Markush format, into multiple restriction Groups. The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 7th edition of the M.P.E.P. (July 1998, February 2000 Revision) at § 803.02 regarding restriction requirements in Markush-type claims:

> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.
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> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility**.

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

First, the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction." Withdrawal of the restriction requirement as between the **ten** specific sequences recited in claim 15 should be made on that basis alone.

Second, **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention.

Specific provisions of the M.P.E.P. strongly support a finding of unity of invention among the sequences recited in claim 15. Here, claim 15 specifically requires the use of antisense by ten sequences, each of which is targeted to and modulates the function of the same bacterial structural RNA species, specifically, 16s rRNA. The target is the same in each case: untranslated structural RNA. Accordingly, the instant antisense sequences are neither structurally nor functionally unrelated. Therefore, unity of invention exists as to Applicants' claimed invention and the restriction is improper.

D. Regardless of whether the unity of invention standard is applied, a simultaneous search of the sequences recited in claim 15 would not impose an undue burden on the Examiner

Applicants respectfully submit that there is minimal additional burden on the Examiner to search ten sequences, a number that has been determined to constitute a reasonable number for examination purposes according to M.P.E.P. § 803.04, especially in view of the fact that each of the nucleotide sequences includes less than 22 nucleic acid residues, and the fact that a search of all 34 sequences recited in claim 35 of the parent application, U.S. Serial No. 09/726,774, filed November 29, 2000, was previously conducted without restriction or any alleged undue burden.

E. Election of one (1) antisense sequence

In the event that the Examiner does not withdraw the requirement to elect among the 10 antisense sequences recited in claim 15, Applicants hereby provisionally elect, with traverse, **SEQ ID NO:30** for examination in the present application.

III. Amendments

Non-elected claims 1-14 and 30-34 are cancelled without prejudice.

Claims 23 and 25 are cancelled are cancelled without prejudice. Applicants have amended claim 15 to incorporate various limitations of previous claims 23 and 25, such that newly amended claim 15 requires that the targeting sequence be selected from the group consisting of SEQ ID NOs: 15, 16, 21-25, and 28-30. Support for this amendment may be found in the claims as originally filed.

No new matter is added by way of these amendments.

CONCLUSION

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is cordially invited to telephone the undersigned counsel at (650) 838-4341 to arrange for such a conference.

No fees are believed due with this communication. However, the Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-2207.

Respectfully submitted,
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